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Appl. No. 10/759,732
Amendment dated March 27, 2006
Reply to Office Action of January 29, 2006

PATENT

REMARKS/ARGUMENTS

STATUS OF THE CLAIMS

Claims 1-17, 19-28, and 36-44 are pending. Claims 18 and 29-35 are withdrawn from consideration. Claims 45-47 are canceled.

ELECTION/RESTRICTION

Claims 45-47 are canceled without prejudice as directed to a non-elected species. Applicants reserve the right to seek prosecution of claims 45-47 in subsequent applications.

OBJECTIONS TO THE SPECIFICATION

In response to the formal objections to the specification, Applicants have amended the specification as requested by the Examiner. As such, Applicants respectfully submit that the objections to the specification have been overcome.

REJECTIONS UNDER 35 U.S.C. § 102(b) INGLE

Claims 23-28 and 36-44 are rejected as allegedly anticipated by USPN 6,091,995 (hereinafter "Ingle"). This rejection is respectfully traversed as follows.

Claim 23 recites a system for treating incontinence of a patient having a collagenous pelvic tissue. The system comprises a probe body and at least one energy delivery element. The probe body is alignable with the collagenous pelvic tissue so that an intermediate tissue is disposed therebetween. The energy delivery element is supported by the probe body. The at least one energy delivery element is capable of heating, from the aligned probe body, a treatment volume of at least 300 cubic millimeters of the collagenous tissue. From the aligned probe body, the energy delivery element is capable of heating the treatment volume to a temperature of at least 70°C for a time of at least 30 seconds, so that the collagenous pelvic tissue contributes to continence. An energy delivery element capable of heating a treatment volume of at least 300 cubic millimeters from the aligned probe body can be understood with reference to Figs. 6, 6A, 16A to 16D and the associated text in paragraphs 57, 74 and 75 of the present

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application. Energy delivery to provide a treatment volume of at least 300 cubic millimeters can be understood with reference to Figs. 14, 15, 23 and the associated text in paragraphs 70, 72 and 84 of the present application.

As the Examiner certainly knows and appreciates, a single cited art reference must teach each and every element of the claim to establish anticipation under 35 U.S.C. § 102. M.P.E.P. § 2131. The Court of Appeals for the Federal Circuit has held that, "the identical invention must be shown in as complete detail as is contained in the ... claims." [*Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989)]

Applicants fail to see where or how Ingle teaches all of the elements recited in claim 23. In particular, Applicants fail to see where or how Ingle shows a treatment volume of at least 300 cubic millimeters of tissue from the aligned probe body. The Examiner has taken the position that the system of Ingle is inherently capable of heating, from the aligned probe body, a treatment volume between about 300 cubic millimeters and about 800 cubic millimeters. [Office Action of December 29, 2005, page 4] Applicants respectfully disagree.

As the Examiner well knows, to establish inherency the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. [MPEP § 2112, *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)]

To rely on inherency the Examiner must show that a treatment volume of at least 300 cubic millimeters from an aligned probe body is necessarily present in Ingle. Applicants respectfully submit that Ingle describes sweeping the probe so that a treatment volume of at least 300 cubic millimeters from the aligned probe body is not necessarily present in Ingle. If the Examiner maintains this rejection, Applicants respectfully request that the Examiner show how heating a treatment volume of at least 300 cubic millimeters from the aligned probe body is necessarily present in Ingle.

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Claims 24-28 and 38-44 are allowable as depending on allowable claim 23 and reciting additional novel combinations of claim elements.

For the reasons discussed above, the withdrawal of this § 102 rejection is respectfully requested

REJECTIONS UNDER 35 U.S.C. § 103(a) INGLE

Claims 1-17 and 19-22 are rejected as allegedly obvious in view of Ingle. This rejection is respectfully traversed as follows.

Claim 1 recites a method for treating incontinence. The method comprises aligning a probe body with a collagenous pelvic tissue, and heating a treatment volume of at least 100 cubic millimeters of the collagenous tissue using the aligned probe body.

As the Examiner certainly knows and appreciates, *prima facie* obviousness requires that the prior art references, alone or in combination, teach or suggest all the claim limitations. [M.P.E.P. § 2143.03; *In re Royka*, 180 U.S.P.Q. 580 (CCPA 1974)] In the present case, several of the claimed limitations, as discussed below, have not been shown to be reasonably disclosed or suggested by the cited reference, Ingle. Secondly, no suggestion or motivation, either in the cited reference or in the knowledge generally available to one of ordinary skill in the art, has been cited by the Examiner for the proposed modifications of the reference teaching so as to produce the claimed invention. [M.P.E.P. § 2143.01; *In re Fine*, 5 U.S.P.Q.2d 1596, (Fed. Cir. 1988)] Applicants also note that even where the level of ordinary skill in the art is high, the Examiner must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. [*In re Rouffet*, 149 F.3d 1350, 47 USPQ2d 1453, 1459 (Fed. Cir. 1998)] The Examiner is not permitted to rely merely on the level of ordinary skill in the art in making an obviousness rejection. [See *Id.* at 1458]

First, the Examiner acknowledges that Ingle fails to describe or suggest heating a treatment volume of at least 100 cubic millimeters using the aligned probe body. [Office Action, page 6]

Second Applicants respectfully submit that the Examiner has not shown a suggestion or motivation to modify Ingle so as to heat a treatment volume of at least 100 cubic

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millimeters using the aligned probe body. Although the Examiner points to treatment temperatures with electrodes adapted to engage the fascia surface (col. 4, lines 29-33), the Examiner has failed to provide any specific suggestion or motivation, known to one of ordinary skill in the art or present in the Ingle reference, that would suggest or motivate modification of Ingle to heat a treatment volume of 100 cubic millimeters using the aligned probe body. Applicants respectfully submit that the Examiner's reliance on the level of skill in the art to determine the optimal treatment area is not sufficient to establish obviousness and fails to show a suggestion or motivation to treat a volume of tissue of at least 100 cubic millimeters from the aligned probe body. If the Examiner maintains this rejection, Applicants respectfully request that the Examiner provide specific reasons which would motivate one of ordinary skill in the art to modify Ingle to heat a treatment volume of at least 100 cubic millimeters using the aligned probe body per *Rouffet*.

Claims 2-17 and 19-22 are allowable as depending on an allowable claim 1 and reciting additional novel combinations of claim elements.

For the reasons set forth above, Applicants respectfully request that this § 103 rejection be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103 INGLE IN COMBINATION WITH PRESTHUS

Claims 36 and 37 are rejected as allegedly obvious over Ingle in combination with USPN 6,685,623 (hereinafter "Presthus"). Applicants respectfully traverse as follows.

To be relied upon as a prior art reference under § 103, the reference must first qualify as prior art under § 102. [MPEP § 2141.01]

First, Presthus is not prior art under § 102(a). The present application claims priority to provisional patent application serial no. 60/440,711, (hereinafter '711 application), filed January 16, 2003. Support for dependent claims 36 and 37 can be found in Figs. 7A to 7D and paragraphs 48 to 50 of the '711 application. Support for independent claim 23, on which claims 36 and 37 depend, can be found in paragraphs 8 and 12 of the '711 application. Thus, the subject matter of claims 36 and 37 has an effective filing date of January 16, 2003, which is before publication of Presthus on May 22, 2003. Because the subject matter of claims 36 and 37

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has an effective filing date before Presthus was published, Presthus is not prior art under § 102(a).

Second, Presthus cannot be used as § 102(e) prior art under § 103. In particular, Applicants note that 35 U.S.C. § 103(c)(1) precludes reliance on a reference which qualifies as prior art under § 102(e) where the reference and the claimed invention are both owned by the same entity. The present application and Presthus are both assigned to the same entity, Solarant Medical (formerly SURx, Inc.). As such, Presthus is available as § 102(e) prior art in this § 103 rejection.

For the reasons set forth above, Applicants respectfully request that this rejection of claims 36 and 37 be withdrawn.

REJECTIONS UNDER 35 U.S.C. § 103 INGLE IN COMBINATION WITH ROY

Claim 36 is rejected as allegedly obvious over Ingle in combination with USPN 6,156,060 (hereinafter "Roy"). Applicants respectfully traverse as follows.

In addition to the other patentable elements set forth above with regard to claim 23 on which claim 36 depends, claim 36 recites a guide body disposable within a urethra, so as to register a position of the treatment volume along an axis of the urethra.

The Examiner has failed to show that the combination of Ingle and Roy teach or suggest all of the limitations recited in claim 36. The Examiner acknowledges that Ingle does not disclose a guide body disposable in the urethra. [Office Action, page 12] While Roy may disclose a rigid shaft used to support a probe body for treating a target tissue (col. 9, lines 16-23), for example endopelvic fascial tissue, the Examiner has not shown that the probe body of Roy is disposable within the urethra. Further, the Examiner has not shown in the cited text (col. 9, lines 16-23) or figures cited therein (Figs. 5B and 5C) that the guide body of Roy provides registration of the treatment along an axis of the urethra. Applicants respectfully request that if the Examiner maintains this rejection, the Examiner show where Roy describes or suggests a guide body disposable in the urethra, for registration of a treatment volume along an axis of the urethra. As the Examiner has failed to show that Roy makes up for the deficiencies of Ingle, all of the limitations recited in claim 36 have not been shown.

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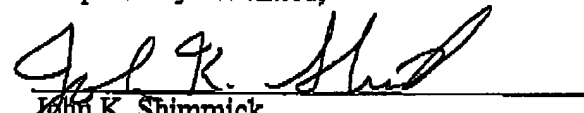
For the reasons set forth above, Applicants respectfully request that this rejection of claim 36 be withdrawn.

CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 415-576-0200.

Respectfully submitted,


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